

REMARKS

The Office Action dated May 22, 2002 has been carefully reviewed and the foregoing amendments are made in response thereto. In view of these amendments and the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Applicants respectfully submit that no new prohibited matter has been introduced by the amendments. Written description support for the amended claims can be found throughout the specification and in the original claims. Claims 1, 3 and 6-12 are pending in the present application.

Summary of the Office Action

1. The embodiments of amended claims 1 and 3 directed to a method of screening or detecting cancer comprising detecting the presence of a protein comprising SEQ ID NO: 3, wherein the presence of the protein is indicative of a "predisposition" to cancer have been withdrawn from consideration as being drawn to a non-elected invention.

2. Claim 5 was objected on the grounds that it does not further limit claim 1.

3. Claim 10 was objected for use of the language "comprising comprising" as being redundant.

4. Claim 10 was objected on the grounds that the clean copy does not correspond with the corrected version.

5. Claim 5 was rejected under 35 U.S.C. 112 (second paragraph) on the grounds that it lacked antecedent basis in claim 1. Claim 9 was rejected under 35 U.S.C. 112 (second paragraph) on the grounds that it lacked antecedent basis in claim 3. The remaining rejections of claims 1-9 under 35 U.S.C. 112 (second paragraph) were withdrawn.

6. The rejection of claim 5 under 35 U.S.C. 112 (first paragraph) on the grounds that the specification does not enable the skilled artisan to use the invention commensurate in scope with these claims was maintained. The remaining rejections of claims 1-4 and 6-11 under 35 U.S.C. 112 (first paragraph) were withdrawn.

7. Claims 1, 3, 5-8 and 10-11 were rejected under 35 U.S.C. 102(a) as being anticipated *Molloy et al.* (1997) Electrophoresis 18, 2811-2815. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,066,724 was withdrawn.

8. The rejection of claims 1-11 have been rejected under 35 U.S.C. 101 for lack of utility was withdrawn.

9. The rejection of Claims 1-9 and 11 have also been rejected under 35 U.S.C. 112 (first paragraph) on the grounds that the specification does not enable the skilled artisan to use the invention commensurate in scope with these claims.

Response to the Office Action

The embodiments of amended claims 1 and 3 directed to a method of screening or detecting cancer comprising detecting the presence of a protein comprising SEQ ID NO: 3, wherein the presence of the protein is indicative of a “predisposition” to cancer were withdrawn from consideration purportedly because they are drawn to a non-elected invention. Applicants bring to the attention of the Examiner that the steps in the screening method of claims 1 and 3 for detecting for the presence of a protein comprising SEQ ID NO: 3 do not differ when determining a predisposition to cancer, when compared to detecting the presence of cancer. The method for detecting a protein comprising SEQ ID NO: 3, however, produces two populations in subjects testing positive, those who have cancer, and those who are predisposed to cancer. In light of the fact that the steps in the claimed methods are identical and the screening identifies both a predisposition to cancer, or the presence of cancer, Applicants respectfully submit that claims 1 and 3 do not contain embodiments directed to separable inventions. Applicants therefore request that those embodiments withdrawn in the Office Action be rejoined with the claimed subject matter in claims 1 and 3.

Claim 5 was objected on the grounds that it does not further limit claim 1. Applicants have cancelled claim 5 without prejudice or disclaimer, therefore the rejection is moot. Claim 10 was objected for use of the language “comprising comprising” as being redundant. Applicants have amended claim 5 to correct this typographical error and respectfully request that the rejection be withdrawn. Claim 10 was also objected on the grounds that the clean copy does not

correspond with the corrected version. Applicants have also amended claim 10 and provided a marked up copy of the amendments to confirm the nature of the amendments. Applicants therefore submit that the objection is moot and request that it be withdrawn.

Rejection Under 35 U.S.C. 112 (second paragraph)

withdraw
Claim 5 was rejected under 35 U.S.C. 112 (second paragraph) on the grounds that it lacked antecedent basis in claim 1. Applicants have cancelled claim 5 and respectfully submit that the rejection is moot. Claim 9 was rejected under 35 U.S.C. 112 (second paragraph) on the grounds that it lacked antecedent basis in claim 3. Applicants have amended claim 9 so that it properly refers to the subject matter of claim 3. In light of the amendment, Applicants respectfully submit that the rejection is moot, and therefore request that the rejection of claim 9 under 35 U.S.C. 112 (second paragraph) be withdrawn.

Rejection Under 35 U.S.C. 112 (first paragraph)

withdraw
The rejection of claim 5 under 35 U.S.C. 112 (first paragraph) on the grounds that the specification does not enable the skilled artisan to use the invention commensurate in scope with these claims was maintained. Applicants have cancelled claim 5 without prejudice or disclaimer and solely for expediting the prosecution of the present application, therefore the rejection is moot.

Rejection Under 35 U.S.C. 102(a)

withdraw
Claims 1, 3, 5-8 and 10-11 were rejected under 35 U.S.C. 102(a) as being anticipated Molloy *et al.* (1997) Electrophoresis 18, 2811-2815. Applicants bring to the attention of the Examiner that Molloy *et al.* was published after the priority date of the present application, which is a national phase application of PCT/AU98/00071. Specifically, the present application has a priority date of February 7, 1997 based on Australian application PO 5009, while Molloy *et al.* has a publication date of December 18, 1997 (see attached abstract with publication date). In light of this fact, Applicants submit that the cited reference is not available as prior art and respectfully request that the rejection be withdrawn. Applicants are willing to provide a certified *available check*

copy of the priority application in the event it was not forwarded to the U.S. Patent Office by the International Bureau when the national phase of International Application PCT/AU98/00071 was entered in the United States.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made" as required by the rules.

If there are any other filing or claim fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for any extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should be charged to our Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 9 has been amended as follows:

9. (Once Amended) The method according to claim 3 where the detecting step (c) involves direct or indirect analysis using [~~labelled~~] labeled probes specific for [~~the disease indicator or marker in an immunoassay or radioimmunoassay~~] a protein having a N-terminal amino acid sequence comprising SEQ ID NO: 3.

Claim 10 has been amended as follows:

10. (Thrice Amended) An isolated protein which is detectable in tears and has a [an] N-terminal amino acid sequence [~~comprising~~] comprising SEQ ID NO: 3.